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SERIAL NUMBER	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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EXAMINER
GUEST, S

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ART UNIT	PAPER NUMBER
186	5

DATE MAILED: 05/24/91

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

☒ This application has been examined ☒ Responsive to communication filed on 12/13/90 + 1/7/91 (7/23/90) ☐ This action is made final.

A shortened statutory period for response to this action is set to expire 3 month(s), 0 days from the date of this letter.
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

1. ☒ Notice of References Cited by Examiner, PTO-892.
2. ☒ Notice re Petent Drawing, PTO-948.
3. ☒ Notice of Art Cited by Applicant, PTO-1449.
4. ☐ Notice of Informal Petent Application, Form PTO-152
5. ☐ Information on How to Effect Drawing Changes, PTO-1474.
6. ☐ _____

Part II SUMMARY OF ACTION

1. ☒ Claims 1-7 are pending in the application.
   Of the above, claims 1-3 are withdrawn from consideration.
2. ☐ Claims _____ have been cancelled.
3. ☐ Claims _____ are allowed.
4. ☒ Claims 4-7 are rejected.
5. ☐ Claims _____ are objected to.
6. ☒ Claims 1-7 are subject to restriction or election requirement.
7. ☐ This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.
8. ☐ Formal drawings are required in response to this Office action.
9. ☐ The corrected or substitute drawings have been received on _____. Under 37 C.F.R. 1.84 these drawings are ☐ acceptable; ☐ not acceptable (see explanation or Notice re Petent Drawing, PTO-948).
10. ☐ The proposed additional or substitute sheet(s) of drawings, filed on _____, has (heve) been ☐ approved by the examiner; ☐ disapproved by the examiner (see explanation).
11. ☐ The proposed drawing correction, filed _____, has been ☐ approved; ☐ disapproved (see explanation).
12. ☐ Acknowledgement is made of the claim for priority under U.S.C. 119. The certified copy has ☐ been received ☐ not been received ☐ been filed in parent application, serial no. _____; filed on _____.
13. ☐ Since this application appears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.
14. ☐ Other

Restriction to one of the following inventions is required under 35 U.S.C. § 121:

I. Claims 1-3, drawn to a protein growth factor, classified in Class 530, subclass 399.

II. Claims 4-7, drawn to a DNA encoding a growth factor, classified in Class 536, subclass 27.

The inventions are distinct, each from the other because of the following reasons:

Inventions II and I are related as mutually exclusive species in intermediate-final product relationship. Distinctness is proven for claims in this relationship if the intermediate product is useful other than to make the final product (MPEP section 806.04(b), 3rd paragraph), and the species are patentably distinct (MPEP section 806.04(h)).

In the instant case, the intermediate product is deemed to be useful as the DNA sequence can be used as a probe in nucleic acid hybridization assays to quantitate the presence of the protein factor gene, and the inventions are deemed patentably distinct since there is nothing on this record to show them to be obvious variants. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.

§103 of the other invention.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and divergent subject matter, and because the searches for the individual Groups are not coextensive, restriction for examination purposes as indicated is proper.

During a telephone conversation with Scott Meyer on May 7, 1991 a provisional election was made with traverse to prosecute the invention of group II, claims 4-7. Affirmation of this election must be made by applicant in responding to this Office action. Claims 1-3 are withdrawn from further consideration by the Examiner, 37 C.F.R. § 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor if at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

35 U.S.C. §101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter

> or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title.

Claims 4-7 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The growth factor gene as claimed has the same characteristics and utility as the growth factor gene found naturally and therefore does not constitute patentable subject matter. The tests set forth by the court are "A nonnaturally occurring manufacture or composition of matter -- a product of human ingenuity -- having a distinctive name, character, and use." is patentable subject matter. In the absence of the hand of man, the naturally occurring growth factor gene is considered non-statutory subject matter. Diamond v. Chakrabarty, 206 USPQ 193 (1980). Mere purity of a naturally occurring product does not necessarily impart patentability. Ex parte Siddiqui, 156 USPQ 426 (1966). However, when purity results in a new utility, patentability is considered. Merck Co. v. Chase Chemical Co., 273F. Supp. 68 (1967). See also American Wood v. Fiber Disintegrating Co., 90 U.S. 566 (1974); American Fruit Growers v. Brogdex Co., 283 U.S. 1 (1931); Funk Brothers Seed C. v. Kalo Innoculant Co., 33 U.S. 127 (1948).

To overcome this rejection, the Examiner suggests the amendment of the claims to include purity limitations which would distinguish the utility of applicant's product as enabled in the specification from the utility of the source containing the

product in nature. It is further suggested that such limitation include the terminology "purified and isolated" and/or a description of what applicant's product is "free of " relative to its utility as distinguished from that of the natural source.

The following is a quotation of the first paragraph of 35 U.S.C. §112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The specification is objected to under 35 U.S.C. 112, first paragraph, as failing to provide an adequate written description of the invention, failing to provide an enabling disclosure and failing to present the best mode contemplated by applicant for carrying out the invention without complete evidence the human or bovine HGBF-8 gene is known and readily available to the public or complete evidence of the deposit.

The cDNA and gene sequences are biological materials necessary to practice the claimed invention. Because it does not appear that the cDNA, gene, or protein are known and publicly available or can be reproducibly isolated from nature without undue experimentation and because the best mode disclosed by the specification requires the use of the bovine or human gene, deposit of the gene is required. Without a publicly available

deposit of the gene, one of ordinary skill in the art could not be assured of the ability to practice the invention as claimed. Note that the best mode is not satisfied by a written disclosure unless that exact embodiment is absolutely reproducible from that disclosure. If reproducibility of the gene is not established failure to deposit the gene would result in the quality of applicant's best mode disclosure to be so poor as to effectively result in concealment of the best mode contemplated by applicant for carrying out the invention. In re Sherwood, 615 F.2d 809, 204 USPQ 537 (CCPA 1980). Applicant is reminded that the deposit of biological material is a recognized exception to the requirement for a written disclosure only where applicant was unaware of a repeatable process to obtain this material at the time the application was filed.

If deposits have been made under the provisions of the Budapest Treaty, filing of an affidavit or declaration by applicants, assignees or a statement by an attorney of record over his or her signature and registration number stating that each deposit has been accepted by an International Depository Authority under the provisions of the Budapest Treaty, that all restrictions upon public access to deposits will be irrevocably removed upon the grant of a patent on this application and that each deposit will be replaced if viable samples cannot be dispensed by the depository is required. This requirement is necessary when deposits are made under the provisions of the

Budapest Treaty as the Treaty leaves this specific matter to the discretion of each State. Amendment of the specification to recite the date of deposit and the complete name and address of the depository is required. As a possible means for completing the record, applicant may submit a copy of the contract with the depository for deposit and maintenance of each deposit.

If deposits have not been made under the provisions of the Budapest Treaty, then in order to certify that the deposits comply with the criteria set forth in MPEP 608.01(p), items 1-3 regarding availability and permanency of deposits for US patent purposes, assurance of compliance is required. Such assurance may be in the form of an affidavit or declaration by applicants or assignees or in the form of a statement by an attorney of record who has authority and control over the conditions of deposit, over his or her signature and registration number, averring:

a) during the pendency of this application, access to each deposit will be afforded to the Commissioner upon request;

b) all restrictions upon the availability to the public of the deposited biological material will be irrevocably removed upon the granting of a patent on this application;

c) each deposit will be maintained in a public depository for a period of at least thirty years from the date of deposit or for the enforceable life of the patent or for a period of five years after the date of the most recent request for the furnishing of a sample of the deposited biological material, whichever is longest; and

d) each deposit will be replaced if it should become nonviable or non-replicable.

Amendment of the specification to recite the date of deposit

and complete name and address of the depository is required. As a possible means for completing the record, applicant may submit a copy of the contract with the depository for deposit and maintenance of each deposit.

If the deposit in not made before the effective filing date of the application for patent in the United States, a verified statement is required from a person in a position to corroborate that the biological material described in the specification as filed is the same biological material which was deposited in the depository.

Applicant's attention is directed to In re Lundak, 773 F.2d 1216, 227 USPQ 90 (CAFC 1985), MPEP 608.01(p) and 1082 TMOG 59 for further information on current and proposed deposit practice.

The following is a quotation of 35 U.S.C. 103 which forms the basis for all obviousness rejections set forth in this Office action:

> A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
>
> Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the

invention was made, owned by the same person or subject to an obligation of assignment to the same person.

Claims 4-7 are rejected under 35 U.S.C. 103 as being unpatentable over Bohlen (EP 0326075) or Rauvala (EMBO J., 1989) et al. in view of Maniatis et al.. Claims 4-7 are drawn to a human and bovine DNA sequence for heparin-binding growth factor. Bohlen and Rauvala both teach purification of an 18 kd heparin-binding protein, and determine N-terminal sequence information (See section 6 of Bohlen and p.2934 of Rauvala). The references do not teach a the cloning of the cDNA sequence, however Maniatis et al. teach methods of determining the cDNA sequence by screening a library with a probe derived from the N-terminal sequence of a protein.

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to clone the gene for HBGF, thus achieving the invention as a whole for the expected benefits of determining the full DNA and protein sequences and enabling recombinant production of the protein. The cloning procedures are used in the manner taught by the prior art for the purposes taught by the prior art. One would have been motivated to use clone the HGBF gene since the N-terminal sequence of the purified protein had been determined and published. Accordingly, claims 4-7 are prima facie obvious over the prior art, absent sufficient objective factual evidence to the contrary.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shelly Guest whose telephone number is (703) 308-4310. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Group 180 by facsimile transmission. Papers should be faxed to Group 180 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center number is **(703) 308-4227.**

sjg
May 20, 1991

GARNETTE D. DRAPER
PRIMARY EXAMINER
ART UNIT 186